TRANSLATIONAL RESEARCH:
A PUBLIC HEALTH LABORATORY IMPERATIVE

A GREEN PAPER PRESENTED BY THE
APHL INFECTIOUS DISEASE COMMITTEE

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES

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STATEMENT OF PURPOSE

The intent of the Infectious Disease Committee in developing this document was to start a discourse within the public health laboratory community on the role public health laboratories currently play in scientific research of public health importance and the potential for that role to grow and evolve. A "green paper" is defined as a "first-draft document on a specific policy area circulated among interested parties who are invited to join in a process of consultation and debate." So, if after reading *"Translational Research: A Public Health Laboratory Imperative,"* you find that you have many questions, comments, additions, or just a strong urge to debate—then we have done our job.

We invite you to share examples of how your public health laboratory has participated in research projects similar to or different from those described herein. We urge you to provide examples of barriers to implementing research in public health laboratories. In short, we welcome any and all forms of feedback as an integral part of the process of shaping a framework for the role of the public health laboratory in research.

SYNOPSIS

It is clear from the NIH Roadmap[1] that the federal government is placing a strong emphasis on both collaborative science and on translating new scientific discoveries into practical healthcare applications. Such successes will continue to be dependent on scientists across disciplines and from all sectors of the healthcare industry playing a role.

Public health laboratories, as part of the governmental sector, are uniquely positioned to help advance healthcare by participating in public health related research, both individually and with academic and industry partners. Such research activities will enhance the capabilities of public health laboratories, firmly establishing their place at the cutting edge of science. This, in turn, will improve preparedness and benefit all members of the community.

INTRODUCTION

The role of the public health laboratory differs from state to state, and there is no one model that can be seen as representative. In certain states where regulations allow, the public health laboratory performs fee-for-service diagnostic testing as a source of revenue because commercial laboratories are not present in the area or because the public health laboratory is seen as a less expensive alternative, especially for uninsured populations. In the latter case, there is considerable pressure to maintain testing capability at the lowest possible cost and very little opportunity to explore new testing platforms.

While the new platforms may be more sensitive and specific, they are often more expensive for the laboratory, although they end up saving the overall public health system money in the long run by decreasing turnaround-times and making contact investigations more efficient.

Two things are clear. First, public health laboratories are underfunded. Second, to remain viable, effective and prepared, public health laboratories must develop new partnerships.

In other states, in order to avoid competing with commercial and hospital laboratories, the focus has shifted more to a reference role in the identification of rare or emerging diseases, outbreak investigations and public health emergencies. In these cases, the public health laboratory has to be "all things to all people" and maintain preparedness capability for, as yet, unknown emergencies. Though this can result in enhanced capability, capacity is often stretched very thin. While public health laboratories start from different places in terms of capability and capacity, two things are clear: first, public health laboratories are underfunded; second, to remain viable, effective and prepared, public health laboratories must develop new partnerships.

It is very difficult to parse out just how little money is spent on research, let alone *public health* research; however, two estimates put the level of funding in perspective. The Centers for Medicare and Medicaid Services Office of the Actuary produces annual assessments on National Health Expenditures. In 2009, 1.8 cents of every health expenditure dollar went to research in the federal, state and local government sectors.[2] Clearly, this figure would not be solely for public health research. Secondly, the Campaign for Public Health Foundation (in tracking program funding at the CDC) indicated that, in the budget enacted in federal Fiscal Year 2010, 0.47% of the CDC's Core Program budget funded public health research.[3]

WHY HAS PUBLIC HEALTH RESEARCH NEVER ENJOYED ADEQUATE FUNDING?

Hemenway[4] proposed four rationales. First, the benefits of public health prevention programs generally lie in the future. Given the realities of politics, current administrations are reluctant to bear costs for benefits that will be reaped by future administrations.

Second, for public health programs such as vaccination campaigns, the beneficiaries are not individually identified; therefore, the programs are not generally newsworthy, unless there is an adverse event.

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Third, public health leaders tend to be unsung heroes who are not recognized by the general public.

Fourth, some public health measures require tough decisions, are not universally popular and engender strong opposition, especially from special interest groups. Worsening the situation is the current fiscal climate.

In June 2010, APHL published a report on the impact of a diminishing funding stream on public health laboratories.[5] The report emphasized the vital role of state public health laboratories as a major component of the nation's emergency response and, significantly, the need to continue outreach and build new partnerships. The central tenet of this discussion paper is that, in order to grow, public health laboratories must establish themselves as significant players in the scientific community and partner with both academia and industry in performing public health research.

PUBLIC HEALTH RESEARCH VS. PUBLIC HEALTH PRACTICE

It should be noted that public health research is distinct from public health practice.

The traditional role of state and county public health laboratories has been defined by the 11 core functions elucidated by APHL.[6] These functions encompass: (a) disease prevention, control, and surveillance; (b) integrated data management; (c) reference and specialized testing; (d) environmental health and protection; (e) food safety; (f) laboratory improvement and regulation; (g) policy development; (h) public health preparedness and response; (i) public health related research; (j) training and education; and (k) partnerships and communication. It is clear, therefore, that research into new insights and innovative solutions to health problems is considered one of the essential services of public health. It should be noted that public health research is distinct from public health practice. While, at times, the two activities appear within a continuum, in those cases where human subjects are involved, there is a clear dividing line between the two. Hodge and Gostin[7] for the Council of State and Territorial Epidemiologists summarized this situation, which is given in outline here.

PUBLIC HEALTH PRACTICE:

- Involves the collection and analysis of identifiable health data by a public health authority;
- Protects the health of a particular community;
- May involve individuals who did not specifically volunteer;
- Is legally authorized by existing public health law, and specific Institutional Review Board (IRB) approval is not usually required;
- Is designed such that the benefits and risks primarily accrue to the participating community.

PUBLIC HEALTH RESEARCH:

- Involves the collection and analysis of identifiable health data by a public health authority;
- Generates knowledge and is usually published as a scholarly article;
- Involves research subjects who are selected and voluntarily participate with informed consent, as approved by an Institutional Review Board. Alternately, a waiver of informed consent may be obtained if identifying information is not collected;
- Is designed such that the benefits generally accrue to a population beyond the participating community who bear the risks of participation.

PUBLIC HEALTH RESEARCH VS. PUBLIC HEALTH PRACTICE (CONT'D)

PH RESEARCH IN PRACTICE

A good example of public health research comes from the Wisconsin State Laboratory of Hygiene in which the public health laboratory collaborated with scientists and physicians in medical colleges and academia to develop and pilot the first newborn screening test for severe combined immunodeficiency (SCID).[8] The method developed is now being used in other states as they incorporate SCID testing into their newborn screening programs. Similarly, the Minnesota Public Health Laboratory developed a novel method to subtype *Salmonella typhimurium* and *Salmonella enteritidis* using multi-locus variable tandem repeat analysis. The new method was used by the CDC during the recent outbreak of *Salmonella enteritidis* in eggs and will be available for dissemination to other laboratories.[9] Additionally, during the mumps epidemic in 2006, staff from the State Hygienic Laboratory at the University of Iowa worked with the CDC to develop and validate a real-time RT-PCR test for the detection of the mumps virus, which was made available to other state laboratories via APHL and published in a peer reviewed journal.[10]

Clearly, all of these examples demonstrate not only the research phase of the work in posing a question and developing an answer, but the translational aspect in bringing the work to fruition in a practical application that has a positive impact beyond the original laboratory and population as well.

It should be noted that the above definitions for public health research (page 6) focus on clinical research involving human subjects. At this point, even prior to publication, IRB approval or exemption with appropriate de-identification of data may be necessary.

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It is also important to remember the crucial role that the environment plays in both individual and public health. Many state public health laboratories have significant environmental testing programs ensuring the quality of air and water supplies, as well as in the area of chemical preparedness. Similarly, public health studies related to zoonotic and vector-borne diseases involve non-human testing and ecological investigations. Excluding biomonitoring, research in these areas should not involve IRB approval.

POTENTIAL AREAS OF PUBLIC HEALTH RESEARCH

Many academic and governmental scientific institutions perform basic research into fundamental biological processes. This type of basic research is not currently feasible for most public health laboratories since it requires considerable institutional financial commitment and a critical mass of scientists with the time and expertise to compete for external funding. Historically, such investment has paid dividends for those public health institutions with a strong research tradition. Having a collaborative relationship with an academic institution may offer a considerable advantage since it provides an ongoing stream of students who bring in new ideas and energy. However, there remain many areas of directed or applied research that are well suited to scientists within the public health laboratory community. These potentially include:

- Collaboration with government agencies, industry, academia and venture capital companies for development, comparative evaluation, regulatory approval and validation of new technologies or assays and comparison to the other diagnostic methods. In 2007 and 2008, PH laboratories in Virginia, Iowa, California, Massachusetts, Wisconsin and Washington State conducted clinical trials of a CDC-developed influenza molecular detection and subtyping assay. Data from these trials contributed to 510(k) clearance by the Food and Drug Administration in September 2008. This partnership between CDC, APHL and participating state laboratories strengthened national capability to monitor and detect influenza viruses; the availability of this assay contributed to the successful 2009 H1N1 response[11,12].
- Development and implementation of new laboratory methods to enhance surveillance of public health relevance. For example, in 2003, the Minnesota Department of Health, Public Health Laboratory (MDH-PHL) detected erythromycin-resistance in a *Bordetella pertussis* isolate from a case of treatment failure. While erythromycin resistance had been previously described in *B. pertussis*, the mechanism of resistance had not been identified. The MDH-PHL used DNA sequencing to determine that resistance was due to a common mutation associated with erythromycin resistance in other bacterial species[13] and subsequently developed a molecular test method that could be used to detect resistance in the absence of a cultured organism.
- Use of sample repositories to collaborate with academic scientists interested in specific diseases. In a federally-funded study with government and academic partners, a subset of the influenza viruses maintained in the repository of the New York State Department of Health laboratory was used as the basis for the first large-scale whole genome influenza virus sequencing study. The results were published[14] and all sequences were made publicly available via GenBank.
- Public health laboratories may make use of existing microbiological and environmental sample repositories to collaborate with academia and industry for the development and characterization of reference materials for use in quality assurance, test development and research. In 2009-2010, the State Public Health Laboratory in Utah collaborated with the University of Utah to create a biorepository called the Utah BioBank Initiative (UBI). UBI has established a physical, informatics and government infrastructure designed to support the scientific, operational, legal, societal and business aspects of

POTENTIAL AREAS OF PUBLIC HEALTH RESEARCH (CONT'D)

a multi-institutional biorepository. The Utah Public Health Laboratory, following approprate regulatory requirements, has and will make available to the BioBank samples of value to the scientific community. In addition, the Utah Public Health Laboratory will be able to access samples within the repository for research of public health importance (personal communication).

- Support for translational research by working with industry, hospitals and large academic centers carrying out clinical trials (drugs, devices and vaccines) to provide an extended range of diagnostic testing. As an example, the Wadsworth Center within the New York State Department of Health is playing a central role as a reference laboratory and DNA sequencing center for an externally funded multi-site FDA clinical trial of two commercial diagnostic assays for the detection of respiratory agents. The study is in collaboration with a large commercial device manufacturer and four collection sites at academic medical centers across the US (personal communication).

- Similarly, in 2009, the State Public Health Laboratory in Utah partnered with the Department of Defense (DoD) to provide technical assistance and validation for panels for a multi-site FDA certification projection (e.g., Emergency Use Authorization) of an H1N1 assay on the JBAIDS hand-held PCR platform, an instrument widely used by the US military for presumptive testing of biological warfare agents. The project was successful with the EUA received in August 2009.

- Collaboration and data mining with epidemiologists within the local, state or national surveillance network. An excellent example of this sort of public health research was the monitoring of the evolution of West Nile Virus genotypes, which resulted in the detection of the emergence of a new and dominant strain of the virus in the US[15]. This was a participatory effort between local, state and federal public health laboratorians as well as scientists in academia in three countries. Similarly, a laboratory-based surveillance study for Eastern Equine Encephalitis virus from the Massachusetts Public Health Laboratory served as a quantitative basis for mosquito control policies in that state.[16]

- Public policy research. What are the top-priority public health problems? Where should the money and effort go? What new technologies will be used in commercial labs in the near future? What levels of biosafety and biosecurity should we impose on our labs? As an example, APHL is an active partner in the national movement to transform health information from a paper format to easily transmissible electronic data.[17] As all state health departments become critically involved in this essential activity, it will be important for all public health laboratories to stay informed and help guide the way that laboratory data is included. A number of learned articles in the area of public policy research were recently published in a special issue of *Public Health Reports*.[18]

OPPORTUNITIES AND CHALLENGES

ADVANTAGES TO PERFORMING RESEARCH IN A PUBLIC HEALTH ENVIRONMENT

A true scientific community is built on the presence of a critical mass of thoughtful and committed intellectuals who are continually pushing to extend the limits of current knowledge. The ideal public health laboratory is one that is an integral part of such a community and whose dual focus is performing public health laboratory services and developing new insights and innovative solutions to health problems. Acknowledging research as an appropriate and necessary part of the public health mission of the laboratory requires a different way of looking at ourselves, but one that may be forced upon us as many of the traditional functions of diagnosis and detection are assumed by the private sector laboratories and we look for new roles. Developing this mindset may require re-education of the executive leadership and will certainly require reaching out to the other members of the scientific community in which public health laboratories operate.

The performance of research has many clear benefits. It energizes and motivates staff who grow intellectually by learning new skills and becoming involved in the planning and conduct of research. Being published in peer-reviewed journals strengthens the validity of public health laboratories and public health laboratorians as being leaders in their field, as well as being a morale-building and reputation-enhancing activity. Research can also bring additional funds into the laboratory in the form of grants or contracts, which can boost employment in the community. The indirect costs incorporated into grants can be important for the institution, enhancing infrastructure services, such as computer technology, equipment modernization and providing the most effective technologies for public health purposes. If the applied research is in collaboration with industry and involves technology evaluation, it provides a mechanism to bring cutting-edge technologies into the public health laboratory. This, in turn, enhances preparedness and responsiveness. Building robust bridges to other members of the healthcare community is also a public relations exercise of the strongest value, as we demonstrate — by our ongoing participation in the conduct of science — that we are equal partners in the promotion of health.

BARRIERS TO IMPLEMENTING PUBLIC HEALTH RESEARCH

The argument has been made that research is not a priority in difficult fiscal climates, when laboratories are already suffering cutbacks in staff and programs and are struggling to perform basic functions. Moreover, in many states, the requirement to perform research in public health laboratories is not in statute and, therefore, is rarely considered an option. Some public health laboratories do not have the appropriate infrastructure to foster human subjects research, including access to an IRB and, most importantly, an administrative organization that can develop and administer contracts and grants outside of the state structure. Research and contract funds are often time-limited, and programs need to be up and running quickly, so mechanisms for rapid hiring and purchasing

OPPORTUNITIES AND CHALLENGES (CONT'D)

of supplies must be in place. Additionally, some public health laboratories in remote communities have little access to collaborative opportunities with academia or industry. Some states require ownership of intellectual property rights, making it difficult to form partnerships with industry and academia. Lack of links to academia can also limit access to students who are interested in shorter term projects and employment.

An additional hurdle to accessing funds for research is that, for the great majority of grant applications, considerable preliminary data and a history of publication in the area are necessary, as is a finely honed and tightly written grant proposal. Starting from scratch as a new investigator is difficult in this funding climate. The key to overcoming these obstacles is strong leaders who will:

- promote the value of research to executive-level staff in the organization;
- work to change legal statutes to include research as part of the laboratory's mission;
- recruit research-oriented and grant-savvy scientists as program directors;
- advocate for re-investing the financial benefits of research dollars into the public health laboratory rather than the General Fund;
- develop a flexible organizational structure to allow for grant application and administration;
- look for creative ways to negotiate and build partnerships;
- encourage laboratory scientists at all levels to redefine themselves, wear multiple hats and expand their scopes of interest.

WHERE DO WE START?

For change to become well-accepted, it must begin incrementally. In this case, we can start by building on what we do best. All public health laboratories, at some level or another, are performing public health practice funded either by the state government, federal authorities or both. This work can include many approaches, such as developing assays to diagnose a newly emerging disease; surveillance of a particular pathogen; use of a new technology platform that increases the sensitivity, specificity or speed of detection; development of a population baseline for future measurement of toxic chemicals; or defining a new testing algorithm that best suits the current disease situation. Many of these studies are already performed in collaboration with epidemiologists, and making this work the basis for ongoing research collaborations makes good sense. Publication of this public health practice in a peer-reviewed journal generalizes the knowledge accrued and makes it available to other scientists. Publication and presentation at scientific meetings is also essential for full participation in the broader scientific

WHERE DO WE START? (CONT'D)

community and leads to more opportunities for collaboration, as others become aware of the work. A history of publication in a specific field is also necessary to prove expertise if a grant application is to be successful. This "building credibility" approach may require data mining of studies and reaching out to other scientists with appropriate expertise in order to generate a complete study that will be accepted for publication in a well-respected peer-reviewed journal.

In parallel, making contact with scientists and physicians in the local academic, hospital or health care community may result in the recognition of a shared interest in particular topics that can be built into a collaboration and a shared grant application. It is useful to review investigator biosketches on websites of local academic institutions, and to attend local seminars and Grand Rounds to become aware of what types of scientific investigations are already occurring in the community.

POTENTIAL SOURCES OF FUNDING

After expertise has been established by publication, partnerships created, testable hypotheses formed and enough preliminary data accrued, the next step is to look for potential funding sources. It is helpful to have a Research Office or Research Official defined within the organization whose responsibility it is to monitor research opportunities within the organization, build partnerships, monitor federal[19] and pertinent foundation websites and help with budget preparation and grant applications. This is a job that requires experience in research and granting mechanisms and might be filled, on a part-time basis, by an appropriate scientist who is ready to wear another hat or who has moved beyond the bench stage of his/her career.

The two logical sources of federal funds for public health research are the NIH and CDC; however, at this time, it is unlikely that the NIH would provide funds for topics that are clearly public health research, seeing it as a CDC role. CDC is most likely to fund public health practice rather than research. It is probably best to focus in a particular area that is current, and in which the particular public health scientist has expertise, and start small, perhaps as a subcontract on a collaborator's NIH grant or in partnership with small business. The awards for SBIR (Small Business Innovation Research) and STTR (Small Business Technology Transfer) grants are administered through the US Small Business Administration, and an STTR award specifically requires a partnership with a nonprofit research institution.[20] The NIH Exploratory/Developmental Research Grant Award (R21) may also be applicable for specific topics that are closer to traditional research.[21] The Health Resources and Services Administration (HRSA) makes grants to organizations to improve and expand health care services to underserved people, and two of their focus areas (newborn screening and HIV/AIDS) would be very pertinent to public health laboratories.[22] Other potential funding sources for grants and contracts include the Biomedical Advanced Research and Development Authority,[23] the Environmental Protection Agency[24] and foundations.

A recent change in federal funding of large clinical research centers by NIH may be of particular relevance to public health laboratories. The Clinical and Translational Science

WHERE DO WE START? (CONT'D)

Awards (CTSA)[25] were launched in 2006 by the National Center for Research Resources of NIH with the aim of developing teams of investigators from various fields of research who can transform scientific discoveries made in the laboratory into treatments and strategies for patients in the clinic. In particular, one of the five strategic goals is to improve the health of our communities and the nation. To achieve this goal, awardee institutions have a mandate to collaborate with each other and with non-CTSA partners through regional consortia and translational research networks. Currently, there are 55 institutions in 28 states and the District of Columbia that are part of the national CTSA consortium, so they are well distributed geographically. In an effort to bring in as many diverse disciplines as possible, the CTSA consortia members provide competitive funding opportunities for research collaborations with other interested partners.[26]

If public health laboratories can develop advocacy for funds, there is another approach which is timely, and which would build on a real strength. The FDA is currently working through the issues of providing more regulatory oversight and review of laboratory developed tests, especially high-risk assays.[27] Public health laboratories have traditionally held themselves to high standards for validation of new assays and have put in place established validation protocols. In addition, they are very often already performing the gold-standard assays to which the new platforms would be compared, and have repositories of clinical samples that could be used in the validation process. The FDA, if appropriated federal funds, could offer RFAs for third party validation and review of industry-developed assays for which the public health laboratories and other appropriate institutions could compete. While the FDA would be the ultimate approving authority, this would provide them with the advantage that the validation would be performed in an environment that provides a real-world evaluation of the technology.

Another example of an area that public health laboratories might pursue is an emerging field in which the federal government has taken a strong interest because of the potential for adverse health effects. Manufactured nanomaterials are increasingly being used in consumer goods. The assessment of the environmental and health risks associated with use of these engineered materials may provide an opportunity for laboratories to collaborate with both academia and industry[28,29].

CONCLUSION

It is clear that the face of healthcare is changing and that the role of public health laboratories will need to evolve in parallel with other healthcare partners. Public health laboratories need to be proactive to address change and look for innovative opportunities to develop partnerships and integrate themselves fully as members of the scientific and healthcare community. Performing research that is appropriate to the public health mission will help achieve this goal.

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Association of Public Health Laboratories

The Association of Public Health Laboratories is a national non-profit located in Silver Spring, MD, that is dedicated to working with members to strengthen governmental laboratories with a public health mandate. By promoting effective programs and public policy, APHL strives to provide public health laboratories with the resources and infrastructure needed to protect the health of US residents and to prevent and control disease globally.

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